May 4, 2020

Dr. Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hahn:

The coronavirus pandemic creates an unprecedented challenge for the Food and Drug Administration (FDA) and the panoply of laws that Congress has enacted to help America prepare for and respond to public health emergencies, including pandemics. With the nation currently practicing "social distancing" as one of our primary weapons against the virus, Americans are eager to get back to work and connect in person with friends and family. Optimistic projections, however, put an FDA-approved vaccine at least a year and a half away. Drugs or other therapies that fight the virus could be an important bridge between social distancing and a vaccine that would allow us to regain some semblance of normalcy with less fear of severe health consequences.

Fortunately, there are more than 70 clinical trials of potential COVID-19 therapies reportedly in progress, and FDA may consider these drug candidates for an Emergency Use Authorization (EUA) that would allow health providers to immediately administer the products while drug sponsors continue to pursue full FDA approval, which can take more than a decade. In fact, FDA issued an EUA for the emergency use of the investigational antiviral remdesivir on May 1. The potential public health impact of this and other product authorizations shines a new light on the EUA program, which has been used infrequently for unapproved drugs, and raises new questions for its operation.

It is clear that FDA is aware of the monumental scope of the task before it. I appreciate the agency's work to launch the Coronavirus Treatment Acceleration Program (CTAP), which FDA says will "use every available method to move new treatments to patients as quickly as possible." It is also important that FDA is participating in the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership aimed at prioritizing COVID-19 vaccine and drug candidates, streamlining clinical trials, and coordinating regulatory processes and assets. However, limited information is available to the public regarding how either venture will be implemented and interact with existing FDA authorization and approval pathways.

FDA's role as the gatekeeper to the United States' prescription drug marketplace is rarely so visible as it is now. As such, it is imperative that the public have a clear understanding of how FDA will implement its congressionally-delegated responsibilities and steer qualified therapies through regulatory hurdles on the basis of strong scientific evidence. I respectfully ask that FDA provide written answers to the following questions by July 15, 2020:

1. Given the large number of drug candidates currently in the pipeline, how is FDA achieving its public health mission and prioritizing review resources? For example, is FDA applying resources on a "first come, first serve" basis, or focusing resources based on factors like scalability, what products could have the most meaningful impact, or what product could be in clinical trials or available to the public earliest?
2. How will deployment of FDA's review resources be shaped by the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership with the National Institutes for Health, European Medicines Agency, and drug companies?
3. Is ACTIV the only public-private partnership expected to influence the COVID-19 pipeline, or are there plans for additional public-private partnerships in the works?
4. How does FDA plan to get potential COVID-19 therapies through regulatory hurdles? Will the agency need to evaluate data from randomized clinical trials to appropriately determine risk-benefit ratios in order to issue an EUA for a new therapy? Can sponsors use real world evidence to support issuance of an EUA, including case reports and mechanistic rationales, and to what degree?
5. How is FDA working with sponsors to advance manufacturing innovations and support rapid ramp up of manufacturing capabilities, and how does that support differ between BARDA-supported medical countermeasures, BARDA-supported MCMs manufactured in HHS Centers for Innovation in Advanced Development and Manufacturing, and non-BARDA supported MCMs.
6. Is FDA expertise in manufacturing technology available to COVID-19 drug candidates that are not BARDA-supported and/or not supported by HHS Centers for Innovation in Advanced Development and Manufacturing (CIADM)?
7. How will FDA balance public health priorities to ensure that concerns about the impact of an EUA on clinical trial enrollment does not preclude issuance of that EUA, if otherwise appropriate?
8. What tools will FDA use to work with sponsors to ensure robust clinical trial enrollment even in the presence of an EUA?

Thank you for your consideration of this request. If you have any questions, please have your staff reach out to Amanda Lincoln at (202) 224-3424.